### **REMARKS**

Claims 1, and 4-8 are pending. All claims stand rejected. Applicant respectfully requests reconsideration of all rejections in the light of the amendments above and arguments below.

# Claim Rejections-35 USC 112

Claims 1-8 have been rejected under 35 USC 112, second paragraph, on the grounds that the claims are indefinite as to derivatives. The examiner is reminded that claims 2 and 3 are no longer pending, having been canceled by the applicant on 6/5/2002. Therefore, re-rejection of these two claims is inappropriate.

Claims 1 and 8 have been amended (now new claim 9) so as to limit FK-506 to metabolites, but to continue to recite rapamycin metabolites <u>and</u> derivatives. The examiner is reminded that pharmacologically active derivatives of rapamycin are disclosed in the specification on p. 2, lines 20-25, in numbers sufficient to satisfy the criteria of <u>In re Castelli</u>, cited by the examiner in his previous Office Action.

These rejections should be withdrawn.

## Written Description

Claims 1-8 are rejected under 35 USC 112, first paragraph, on an assertion that applicant has not provided sufficient examples of pharmacologically active derivatives and metabolites of FK-506 and rapamycin to enable the generic recitation in these claims. As noted above, claims 2 and 3 had been previously canceled.

The examiner is referred to amended claim 1 and replacement claim 9, and the explanation above. No recitation of derivatives of FK-505 remains in these

It would be appropriate for the examiner to withdraw all of these rejections.

## **Double Patenting**

The examiner continues his rejection of claim 8 over applicant's method patent USPN 6,410,340.

Replacement claim 9 has been now recites only the recombinant 8.4 kDa immunophilin and not the protein isolated from tissues. Hence, the present claim 9 does not read on the kit claim in the issued methods patent.

For this reason, examiner's rejection based on obviousness-type double patenting should be withdrawn.

#### Conclusions

Applicant submits that he has overcome all claim rejections, and that it would be appropriate to pass these claims to issuance.

Respectfully submitted,

Date of signature: 3/16/2004

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